EXHIBIT 5

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TITLE: Drug Wars: Coalition Tactics Make Price Fight Look Like Battle Over Tobacco

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TEXT:

ETHAN POSNER SAW SOME OF THE CLOUDS GATHERING while he was at the Justice Department. As deputy associate attorney general from 1999 to 2001, he oversaw major litigation in the antitrust and civil divisions, and at one point he testified before committees in both houses of Congress about problems with pharmaceutical sales over the Internet.

By the time Posner left for private practice at Covington & Burling in Washington, D.C., last year, the pharmaceutical industry was reeling from a sudden convergence of forces. "It's *The Perfect Storm* over the past year or so," says Posner, who represents some pharmaceutical companies as well as the Pharmaceutical Research and Manufacturers of America (PhRMA).

Like so many weather fronts and patterns coming together in one place at the same time, this "perfect storm" over prescription drug prices is made up of public opinion, consumer groups, regulators, criminal investigators, politicians and plaintiffs lawyers.

The pharmaceutical industry and its legal representatives are now beset by a torrent of suits alleging fraud and predatory pricing, demands for more stringent regulation, and investigation of longstanding practices in patenting, promoting and producing drugs.

Some are saying drug companies might be the next tobacco. Never mind that tobacco kills and prescription drugs save lives.

Consumer groups concerned about skyrocketing prices have come together with plaintiffs lawyers retooled from the tobacco wars, and they have filed suit after suit after suit in the past year or two. A task force of 40 state attorneys

general has begun doing the same--again, much as they did with tobacco.

The new director and chief executive officer of AARP, William Novelli, who came over from an anti-tobacco group, has brought the influential 35-million-member organization of older citizens into the fray. AARP has joined in several lawsuits and added its own lawyers as co-counsel. At the same time, it has launched a $ 10 million print and television advertising blitz.

The Federal Trade Commission has started to look at fraud, abuse and antitrust issues in an industry that is more accustomed to the Food and Drug Administration looking at protocols and plant cleanliness. And $ 88 million of the FBI's budget this year alone is carmarked for health care fraud. Congressional committees are turning up the heat.

While trying to survive the swarm of attacks, the pharmaceutical industry has come up with a public relations program but not a coordinated defense. However, some of the practices being attacked were considered perfectly legal before the storm hit.

Still, the list of challenges goes on.

Besides the spate of civil suits and regulatory concerns, Posner points out that the industry faces a Department of Justice that beefed up forces in the early 1990s to go after health care fraud. DOJ first investigated the clinical laboratory industry and then the major hospital chains. Now, increasingly, the target is drug pricing.

"When you're caught in anything that could be fraud, you're more at risk, and everybody knows you're easier to go after," says Robert Blendon, director of the Program on Public Opinion and Health and Social Policy at Harvard University's School of Public Health. "I don't think the drug companies realized it would all come together because the pieces are all separate. But lawyers and politicians smell issues that look good to juries and voters. This is a substantial issue to older voters--the ones who show up at elections--and newspapers have become sympathetic to the case."

The pharmaceutical industry has plenty of experience with lawsuits over prescription drugs that sometimes injure or kill rather than remedy or cure. Product liability problems are part of the cost of doing business. But this grassroots blizzard of litigation--a process dubbed "regulation through litigation" by former U.S. Labor Secretary Robert Reich--is new for the industry.

The lawsuits and investigations primarily go after three aspects of drug pricing:

. Alleged kickbacks through manipulation of the average wholesale price, known as AWP, that Medicare and Medicaid use to reimburse physicians for certain drugs used in outpatient treatments (such as chemotherapy). The pharmaceutical companies sell drugs they want to promote at a discount to physicians, who in turn are reimbursed by the government programs for the full AWP. The drug companies ensure that higher-priced drugs are used, and the doctors pocket sizeable profits.

. The legal requirement that drug companies charge Medicaid the "best price" or slightly less, which is pegged at what private purchasers pay. Critics say the best price would be lower if drug companies factored in the grants paid to private concerns such as pharmacy benefit managers. These middlemen for employers and insurance companies are rewarded for putting selected drugs on approved lists.

. Alleged abuse of a law aimed at getting generic drugs to the market sooner. Critics say drug manufacturers are filing frivolous patent claims and using other improper means to extend the 20-year patents on certain hugely profitable drugs. In other instances, brand-name manufacturers allegedly enter secret agreements to pay generic drug manufacturers not to copy certain brand-name drugs.

While there are many similarities to the tobacco litigation that led to a $ 200 billion settlement in 1998--with the bulk of the money going to the states and plaintiffs lawyers--there are significant differences in the battle over drug

pricing.

For starters, the feuding that developed between plaintiffs lawyers and the states over the pot of tobacco money seems to have taught state governments a lesson. The Pharmaceutical Pricing Task Force, made up of 40 state attorneys general, has rebuffed attempts by plaintiffs lawyers who had worked with them in tobacco litigation to join the fight against the pharmaceutical companies.

There is, for example, the still-pending suit brought against Illinois by several plaintiffs firms that say they were promised 10 percent of the state's tobacco settlement, which came in at $ 9.1 billion. The firms got $ 121 million through arbitration and are seeking another $ 740 million.

"This is not going to be another windfall for plaintiffs lawyers around the country," says Brett Crow, a spokesman for Ohio Attorney General Betty Montgomery, chair of the drug pricing task force.

AARP did the same. Famed plaintiffs lawyer Richard Scruggs, of Pascagoula, Miss., reportedly approached the group about joining him in suits against pharmaceutical companies. Instead, AARP announced in May that it was joining suits brought by the Prescription Access Litigation Project, a coalition of more than 80 consumer and public interest groups around the country.

While the litigation project is using several plaintiffs law firms, led by the Boston office of Seattle's Hagens Berman, control and direction are in the hands of the consumer groups. "The difference is that this litigation is consumer-driven, and it's not driven by the private bar," says Ahaviah Glaser, the Boston-based project's director. "These consumer groups are up in arms and bringing a different voice to the table and real credence to the claims."

The drug companies have fought back, in part, by initiating litigation to stop states from using preferred drug lists for doctors treating Medicaid patients. The lists usually name lower-cost brand-name and generic drugs, and drug companies wanting their premium drugs on the lists must offer steep discounts or rebates.

PhRMA has filed several lawsuits to end the practice of preferred drug lists. In July, the organization sued the Michigan Department of Health and Human Services and the administrator for Medicare and Medicaid services for approving a preferred list program in Michigan. Other suits have been aimed at individual states, but this one seeks to stop the federal government from even permitting such lists when they require price concessions from the drug companies. PhRMA argues that the state is violating federal law by letting states improperly deny or restrict access to medicines by Medicaid patients.

The appeal of a case PhRMA brought against one state program, Maine Rx, was accepted by the U.S. Supreme Court this year. The program allows state residents who enroll to purchase prescription drugs from participating pharmacies at discounted prices funded by drug manufacturers' rebates. As a further incentive for participation, the state links the program to Medicaid restrictions, requiring doctors to get prior authorization before prescribing drugs that are not part of Maine Rx.

The association argues that Maine's law illegally limits access to drugs for Medicaid patients and violates constitutional restrictions on a state trying to regulate commerce of drug manufacturers outside its borders. The 1st Circuit rejected the argument, holding the program was a prior authorization program permitted under federal law and did not violate the commerce clause. *Pharmaceutical Research & Manufacturers of America v. Concannon, 249 F.3d 66 (1st Cir. 2001), cert. granted*, No. 01-0188.

And in September, the Atlanta-based 11th U.S. Circuit Court of Appeals ruled against PhRMA in a similar case. The association challenged a Florida law requiring physicians to obtain prior approval before prescribing drugs not on an approved list of less-expensive medications. Companies that agree to pay a rebate can be considered for the list. PhRMA argued the Florida list was a "formulary" that did not satisfy federal law that restricts excluded drugs to medications that are ineffective or unsafe. But the court ruled the program was instead a prior authorization program

permitted under federal law. *Pharmaceutical Research and Manufacturers of America v. Meadows,* No. 02-10151.

BACKS AGAINST THE WALL

BUT FOR THE MOST PART, THE DRUG COMPANIES HAVE been on the defensive. They are up against an "iron triangle" of bad publicity, lobbying efforts and litigation, according to Victor Schwartz, the noted tort-reform lawyer and lobbyist in Washington, D.C. And it's all aimed at corporate pocketbooks.

"This is a classic case of the iron triangle," says Schwartz, who explains that the multidimensional attack was perfected by plaintiffs lawyers in the tobacco wars. He says defense firms have been slow to adopt equally varied and effective responses. "This isn't just the filing of a case somewhere; it's a concerted action of litigation, publicity and government activity among those friendly to the view that drug pricing should be changed."

One of the more successful plaintiffs lawyers in the tobacco wars, and now the lead lawyer for the multifront, massive litigation brought by the prescription access group, scoffs at critics.

"They might derisively call this 'regulation through litigation,' but someone else might say this is conservative, traditional law enforcement," says Thomas Sobol, who recently left one plaintiffs class-action powerhouse, Lieff Cabraser, Heimann & Bernstein, for another, Hagens Berman. "By enforcing the laws, you can change conduct so the laws aren't broken anymore."

The industry's initial response to the sudden and multipronged attacks has been to run advertisements touting themselves as the industry that changes, improves and prolongs lives. That effort bombed as the legions of critics, and litigants, grew and grew. But PhRMA, the association of the biggest companies, has kept pushing the industry's mantra: Huge sums of money go into research and development--$ 30 billion last year--and if the companies don't make profits (or if they get hurt too much by litigation), the next essential drugs might not come to market.

And in September, the association added to the message machinery, creating a Strategic Communications and Public Affairs Division. It hired noted Washington, D.C., strategist Mark Merritt as a senior vice president. In announcing the move, the *Washington Post* described PhRMA as perhaps "the top health-care political target in town."

One longtime critic of the industry, Stephen W. Schondelmeyer, who teaches pharmaceutical economics at the University of Minnesota, fears that the drug industry's public relations battle will backfire.

At least 17 states are considering or have passed legislation to control drug prices directly by mandating lower prices for Medicare patients. Such a law in Vermont was knocked down in June, but Maine's was upheld in the *Concannon* case.

"My fear is that the drug companies will hold that PR line about developing new drugs for so long, they'll get whacked off at the knees by draconian legislation that overly impacts the market," Schondelmeyer says. "If they keep saying they won't be able to find a cure for grandma, they'll get hit with things that hurt them and society. Drug companies should be talking with policy-makers about distortions in the pricing schemes and how to fix them, not just saying 'What pricing issue?'"

But the drug companies believe the genie was out of the bottle once class-action plaintiffs lawyers entered the fray. "I don't think the big class-action plaintiffs bar is going to be interested in a thoughtful policy debate over drug pricing and innovation," says Posner, who represents some drug companies and PhRMA.

PRONOUNCED LOSSES AS PATENTS EXPIRE

THERE IS A LOT AT STAKE. THE $ 300 BILLION PHARMACEUTICAL industry sold $ 154 billion in prescription drugs in the United States last year, continuing a fast and steady rise in recent years--up from $ 78.9 billion in 1997. Within the next five or so years, analysts say, as much as $ 150 billion in revenues could be lost as patents expire on a number of profitable brand-name drugs and generic versions reach pharmacy shelves.

The wake-up call for the industry, and to some the signal for a feeding frenzy by their opponents, came last year. TAP Pharmaceutical Products Inc., a joint venture of Abbott Laboratories and Takeda Chemical Industries (a Japanese firm), paid $ 875 million as part of a settlement with federal prosecutors who brought related civil and criminal cases alleging fraud in drug pricing. It was the largest penalty ever concerning health care fraud. *U.S. v. TAP Pharmaceutical Products Inc.*, Crim No. 01-cr-10354-wgy (D. Mass.); *U.S. ex rel. Gerstein v. TAP Holdings Inc.*, No. 98-cv-10547-gao; and *U.S. ex rel. Durand v. TAP Holdings Inc.*, No. 00-cv-12618-ao.

In federal court in Boston, TAP pleaded guilty to one count of criminal conspiracy, and the investigation led to indictments of a dozen current and former TAP employees and several physicians accused of accepting kickbacks.

Both federal and state grand juries continue looking into that and other drug pricing matters. Part of the TAP investigation concerned average-wholesale-price arrangements in which drug companies, to promote certain profitable drugs, give doctors discounts on the medications, and the doctors in turn get reimbursement from Medicare at the nondiscounted AWP.

The AWP issue is particularly galling to the pharmaceutical industry. The practice has been no secret, with government recognition going back as far as 1967. And on several occasions when Congress has looked into doing something about it, testimony from physicians, particularly oncologists, has persuaded legislators to leave it alone. The doctors say changing the system would lead to more expensive inpatient treatment for administering the cancer drugs.

"There's no question that many of the attacks are on practices that manufacturers believed in their hearts were legal," says Paul E. Kalb, a Washington, D.C., physician-turned-lawyer who represents some pharmaceutical companies in trouble. "Three or four years ago, if you surveyed manufacturers and asked if AWPs were kickbacks, they'd have looked at you like you were from another planet. They'd say, 'It's the industry practice, and our lawyers advised us it's perfectly acceptable.'"

But while the industry argues that AWP has been an accepted part of the game, drug companies are capitulating. Even before the TAP case, Bayer paid $ 14 million to the U.S. government and 47 states two years ago to settle allegations that the AWP kickbacks to doctors getting reimbursed by Medicaid were illegal under the False Claims Act. It was a qui tam whistle-blower case. *U.S. ex. Rel Ven-A-Care of the Florida Keys Inc. v. Bayer Corp.*, No. 95-1354-civ. (S.D. Fla.).

Mindful of heightened scrutiny, PhRMA in July issued voluntary guidelines concerning free gifts from drug companies to physicians, which have been eyed more and more as possibly illegal inducements to promote certain drugs. Such gifts should "benefit patients and enhance the practice of medicine," according to the new guidelines. That means plastic models of body parts are acceptable, and golf bags sporting the brand names of drugs are not.

But critics say such measures are just Band-Aids given the size and scope of the industry's problems. One concern has been increased scrutiny by the FTC, which is sometimes working with plaintiffs' lawyers. In July, the agency issued a report detailing its investigation of what it calls the pharmaceutical industry's illegal use of loopholes to delay generic versions of profitable drugs. One such loophole is an automatic 30-month delay of generic drug entry into the market when the brand-name company files a new patent on the existing drug. In some cases, multiple delays are granted. Another concerns brand-name companies entering agreements with the first generic maker of a drug to keep the generic off the market for at least six more months.

That report added fuel to congressional attempts to change the 1984 Hatch-Waxman Act, which was intended to speed up the entry of generic drugs but included the delays. The FTC report specifically recommends such changes.

In October, President Bush announced that he was asking the Food and Drug Administration to adopt a new rule closing some of the loopholes noted in the FTC report. The rule would allow drug manufacturers to obtain only one 30-month delay before a generic drug is released and bar them from filing patents for minor features of a product, such as its shape or packaging.

The FTC also has initiated complaints against some companies and entered some private litigation. The agency filed an amicus brief raising antitrust concerns in the case brought against Bristol-Myers Squibb by the Prescription Access Litigation Project in April 2001. That complaint, now in multidistrict litigation in federal court, alleges the drug company filed an improper patent to extend its monopoly on BuSpar, a very profitable and widely prescribed anti-anxiety drug. *In re Buspirone Antitrust Litigation*, MDL No. 1410 (S.D. N.Y. 2001).

But the FTC suffered a setback in June when an administrative law judge ruled that the agency had "failed to meet its burden of proof" for allegations that Schering-Plough Corp. had illegally paid off a generic drug manufacturer to keep the cheaper brand of a popular drug off the market. FTC File No. 991-0256 (2002).

"That shows that there are weaknesses in the attacks," says one drug company lawyer. "But there's a juggernaut going on."

GRAPHIC: Photo 1, *Drug company attorney Ethan Posner doesn't think class action lawyers want a "thoughtful policy debate."*; Photo 2, *Plaintiffs lawyer Thomas Sobol says these suits against drug companies merely enforce the law*.